



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

JUL 29 2004

Wayne H. Matelski  
Arent Fox, PLLC  
1050 Connecticut Avenue, N.W.  
Washington, D.C. 20036-5339

Re: Docket No. 2004P-0051/CP1

Dear Mr. Matelski:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated February 3, 2004. Your petition requests that FDA determine whether Dyclone (dyclonine hydrochloride) Topical Solution 0.5% and 1.0% was withdrawn from sale for reasons of safety or effectiveness.

FDA has yet to reach a decision on your petition because of the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Axelrad", is written over the typed name.

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

2004P-0051

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